THE IMPORTANCE OF STEREOACUITY IN A VIRTUAL REALITY MODEL OF STRABISMUS SURGERY

by

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Dalhousie University is located in Mi'kma'ki,
the ancestral and unceded territory of the Mi'kmaq.
We are all Treaty people.

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Abstract

Stereopsis is a binocular phenomenon that gives rise to high-level depth perception. In simulated intraocular surgeries, several studies found subjects with normal stereopsis performed simulated surgery with better accuracy and efficiency than subjects with reduced or absent stereopsis. There is little known about the role of stereopsis in extraocular muscle surgery. This study used a novel virtual reality strabismus simulation program to investigate the role of stereopsis in strabismus surgery. The purpose of this study was to determine if the reported longstanding absence of stereopsis in strabismic individuals impacts the accuracy, completion speed, and efficiency of a task simulating the insertion of a needle into the edge of a rectus muscle (an important step in strabismus surgery). We planned to compare the performance between surgically inexperienced adults with normal stereopsis and those with reported longstanding absence of stereopsis. However, our surgical simulation program failed to collect the appropriate data due to technological and design limitations. This study discusses considerations we recommend for the future development of a virtual reality model of strabismus surgery, including validation of a surgical model, the use of new technology and augmented reality, and the use of tactile or haptic feedback in surgical simulation.

List of Abbreviations Used

2D	Two dimensional
3D	Three dimensional
ACMGE	The Accreditation Council for Graduate Medical Education
Arcsec	Seconds of Arc
CaRMS	Canadian Resident Matching Service
cm	Centimetres
D	Diopters
E	Esophoria
E(T)	Intermittent Esotropia
E-ETDRS	Early Treatment for Diabetic Retinopathy Study (Electronic)
ET	Esotropia
H	Hyperphoria
H(T)	Intermittent Hypertropia
HT	Hypertropia
HTC	High Tech Computer Corporation
IWK	IWK Health
LE	Left eye
m	Metres
M&S	M&S Technologies
MANOVA	Multivariate analysis of variance
mm	Millimetres
N6	Near vision, size 6 (normal vision)

PC	IBM Personal Computer
PGY	Post Graduate Year
PH	Pinhole
RE	Right eye
REB	Research Ethics Board
SL	Single letters
TETRAS	The Essential Tremor Rating Assessment Scale
TNO	Netherlands Organisation for Applied Scientific Research
TRG	Tremor Research Group
UK	United Kingdom
VR	Virtual Reality
X	Exophoria
X(T)	Intermittent Exotropia
XT	Exotropia

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Chapter 1 Introduction

1.1 Stereopsis

Stereopsis is a sensory phenomenon of binocular vision that allows for depth perception or three-dimensional (3D) perception. Stereopsis is created by the two eyes viewing the world from slightly different viewpoints (Ogle et al., 1967, p. 292). In humans, the eyes are typically about 6cm apart. This interocular distance results in a subtle difference in each eye's viewpoint. The image disparity between the eyes gives cues indicating the relative distance an object is from the viewer (Wheatstone, 1997).

To experience stereopsis, there must be binocular single vision and sensory fusion. Binocular single vision is the superimposition of corresponding retinal images from each eye perceived together as a single image (Von Noorden & Campos, 2002, pp. 20–22). Each point of the retina has a corresponding point on the other eye, in the visual space around the point of fixation, the locus of intersections of these corresponding points creates the horopter. In the visual space surrounding the horopter, points with slight retinal disparity from each eye can be perceived as one image. This visual space where disparate retinal images can be fused is known as Panum's fusional area (Hampton, 1982).

1.2 Monocular Depth Cues

While binocular conditions are required for stereopsis, under monocular conditions other depth cues persist allowing for estimates of depth and the perception of three-dimensional scenes. Relative size, linear perspective, contour interaction, texture gradient, shading and occlusion are just a few examples of monocular cues. Figure 1.1 shows examples of pictorial depth cues. Relative size is based on the probable assumption that of two images on a two-dimensional picture, the larger image is likely

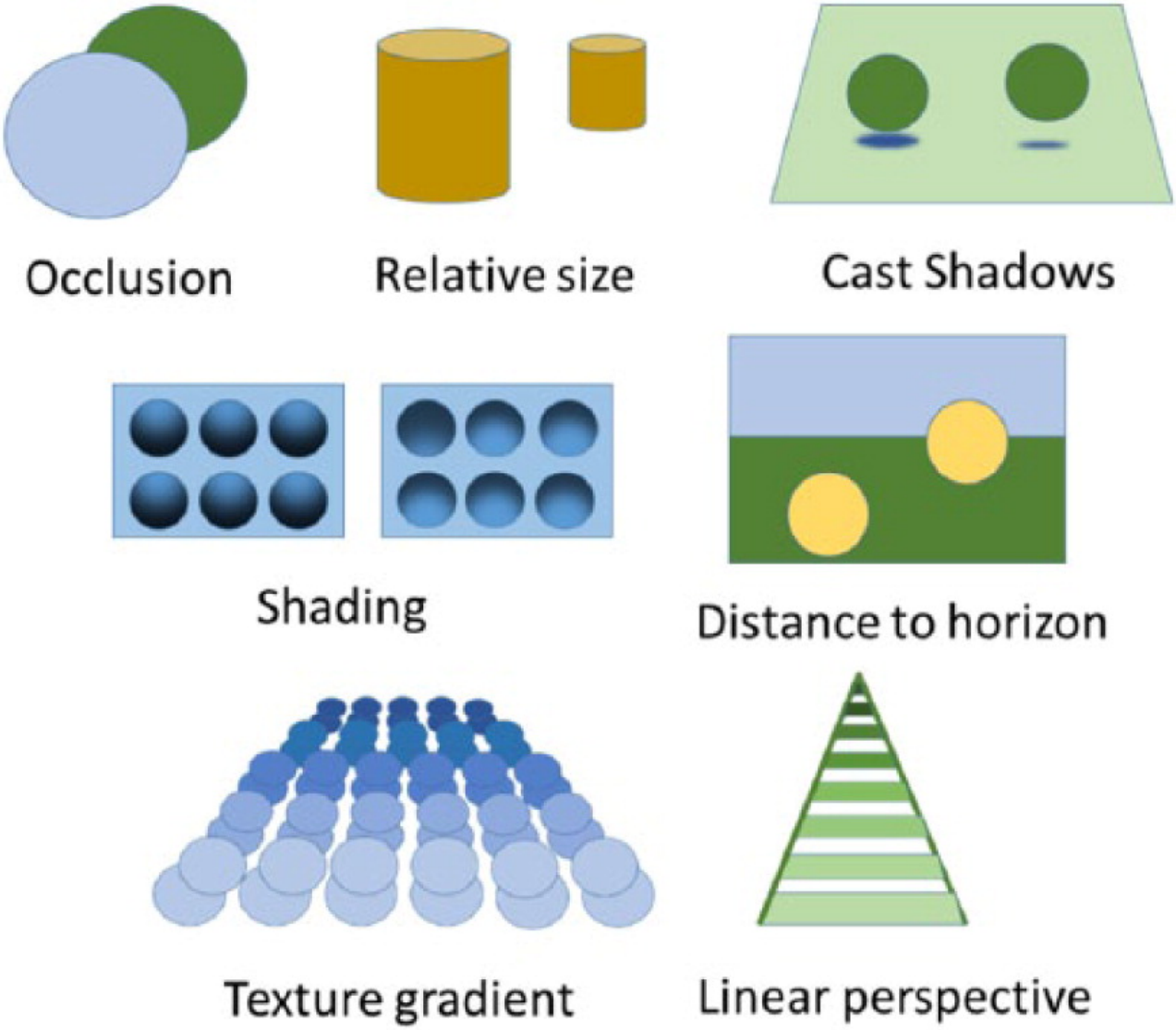
nearer to the observer than the smaller one. Linear perspective depicts images lower on the plane as nearer to the viewer and luminance contrasts cause the appearance of stronger contrast images to be nearer. (Guibal & Dresp, 2004). Geometric depth cues such as contour intersection and partial surface occlusion also work alongside other cues to give more details of relative depth (Dresp-Langley & Reeves, 2020). As these cues do not rely on binocular viewing or motion to be perceived, they are sometimes referred to as pictorial cues and can be seen in paintings and photographs.

Motion parallax is another monocular depth cue created by the movement of the viewer, or the translation of images or objects across the field of view creating the perception of relative depth (Vienne et al., 2020). Figure 1.2 illustrates objects that appear to move faster are perceived as nearer to the viewer (Bradshaw et al., 2000). Motion parallax is important for the sensation of depth in virtual reality simulations, and creating realistic viewing conditions (Vienne et al., 2020).

Monocular depth cues can be helpful in perceiving depth; however, they can be less accurate and may be more susceptible to illusions or incorrect estimates of depth than stereoacuity (Wright et al., 2013). A study on the relationship between fine motor skills and sensory fusion found performance on most fine motor tasks to be significantly better in subjects with sensory fusion compared to subjects with no sensory fusion. Those with normal stereoacuity performed the best on all assigned motor skill tasks (O'Connor et al., 2010).

Figure 1.1

Illustration of basic pictorial depth cues



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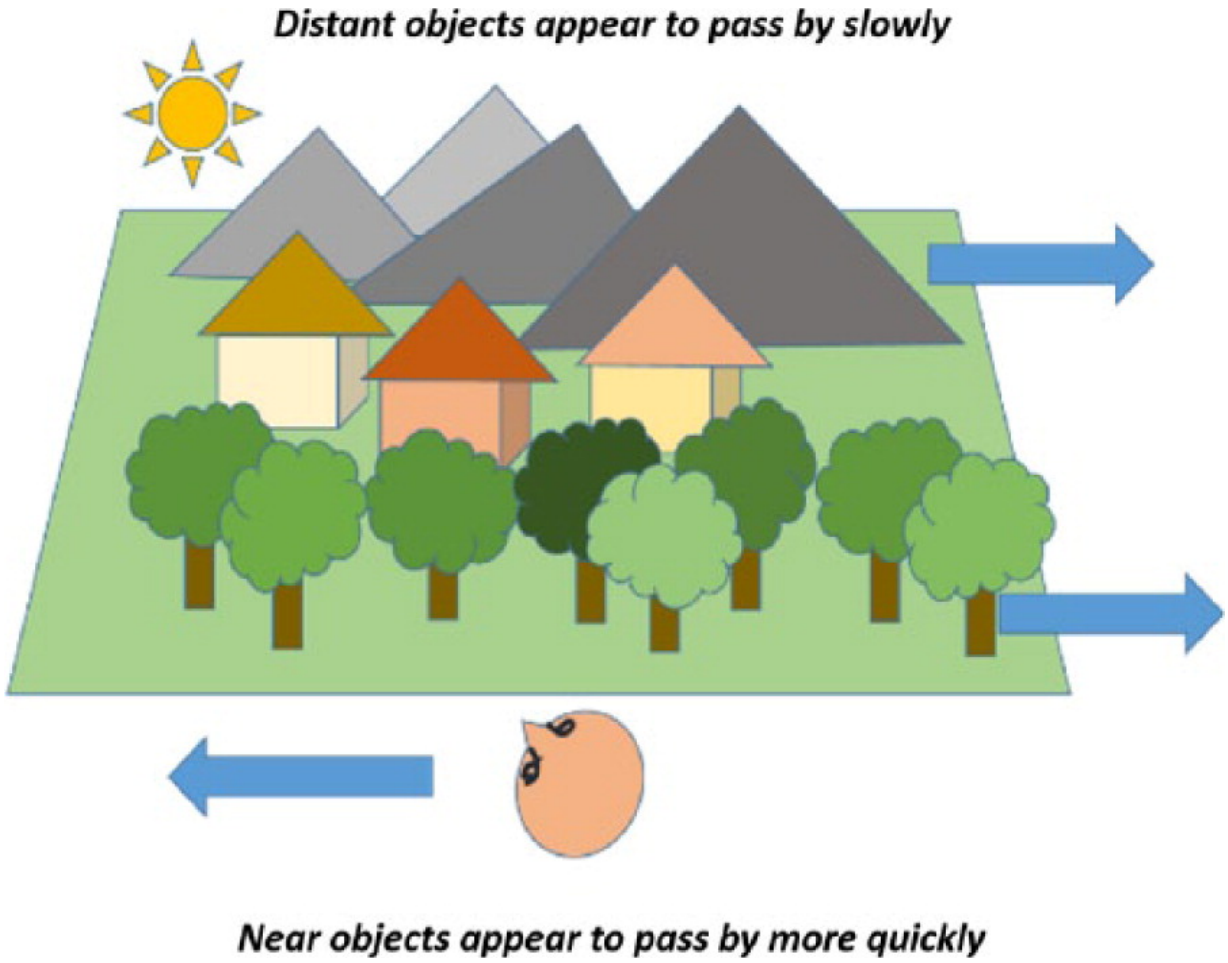
Note. From "Depth Perception of Surgeons in Minimally Invasive Surgery" by R. Bogdanova, P. Boulanger, and B. Zheng. *Surgical Innovation;23*(5), 515-524.

Figure 1.2

Illustration of motion parallax



Note. From "Depth Perception of Surgeons in Minimally Invasive Surgery" by R. Bogdanova, P. Boulanger, and B. Zheng. *Surgical Innovation.;23*(5), 515-524.

1.3 Binocular vs Monocular Viewing Depth Cues

The human visual system utilizes binocular and monocular cues to process the three-dimensional (3D) information necessary for the estimation of spatial awareness and object sizes. One thing that remains unclear is how these different depth perception processes interact with

each other in the visual system. The perception of size and depth have been discussed in multiple studies. In a study of the reaching behaviours of 5 and 7 month old infants, the authors found higher accuracy in binocular viewing conditions compared to when only monocular cues, such as size, motion parallax, and accommodation, were available (Granrud et al., 1984) . Some studies have reported that the ability to perceive the true size of objects, regardless of different viewing distances, was significantly impaired when viewing conditions transitioned from binocular to monocular viewing (Hastorf & Way, 1952; Holway & Boring, 1941; Taylor & Boring, 1942). In contrast, some literature has suggested that the addition of binocular cues is redundant and has no advantage over monocular depth cues when it comes to object size perception. These studies found that size perception remained consistent irrespective of the viewing conditions (Leibowitz et al., 1967; Leibowitz & Dato, 1966; Leibowitz & Harvey, 1967).

Virtual reality allows for the manipulation of visual scenes that would not be feasible in real-world viewing. One recent study utilized a head-mounted virtual reality system to examine and compare the effects that binocular and monocular viewing has on object size perception. This study used virtual reality to manipulate and alter the depth cues and compare the amount of object size illusion under the two viewing conditions. The combination of monocular and binocular depth cues was found to have an additive

effect on perceived depth when in agreement. However, when there is a conflict between monocular and binocular cues, monocular cues overrode binocular cues. It is unclear if these findings would still apply in more visually complex scenes and real-world viewing (Yoo et al., 2023).

1.4 Abnormal Stereopsis

Binocular vision and fusion are prerequisites for stereopsis. Thus, abnormal or absent stereopsis can result from disrupted fusion such as with strabismus (a misalignment of the eyes), or decreased vision in one or both eyes (Archer et al., 1986; Joo & Choi, 2023). Monocular viewing conditions have been shown to impair performance in reaching, grasping, and other motor tasks. However, for some motor tasks, those with a long-term absence of stereopsis perform better than those with normal stereopsis in monocular or two-dimensional viewing conditions (Bloch et al., 2015; O'Connor et al., 2010; Servos et al., 1992). In the latter case, the difference in performance under monocular conditions suggests there are monocular adaptations developed to appreciate depth for these tasks in the absence of stereopsis.

1.5 Clinical Evaluation of Stereopsis

Clinical tests for stereopsis screen for the presence of stereopsis or aim to quantify stereoscopic acuity. Stereoscopic acuity, also referred to as stereoacuity, is the smallest disparity in images between the eyes that can be detected and perceived as depth. These thresholds are typically described in terms of the visual angle measured in seconds of arc (arcsec). Two broad categories of clinical tests are random-dot stereograms and contour stereograms (Fricke & Siderov, 1997). In random dot stereogram tests, similar arrangements made up of seemingly random dots are presented to each eye. The dots

forming the intended 3D figure are laterally displaced in one of these arrangements compared to the other. When viewed independently both arrangements appear to be random. However, when viewed simultaneously and fused, a three-dimensional image is perceived due to the binocular pattern recognition of the horizontal disparities in the images presented to each eye. Form recognition arising from binocular pattern recognition is referred to as global stereopsis (Julesz, 1960). In contrast, contour stereograms use monocularly visible forms or contours to create horizontal disparities. When fused, the horizontal disparities give rise to the perception of depth. The process of perceiving depth from disparate contours is referred to as local stereopsis (Fricke & Siderov, 1997; Julesz, 1960).

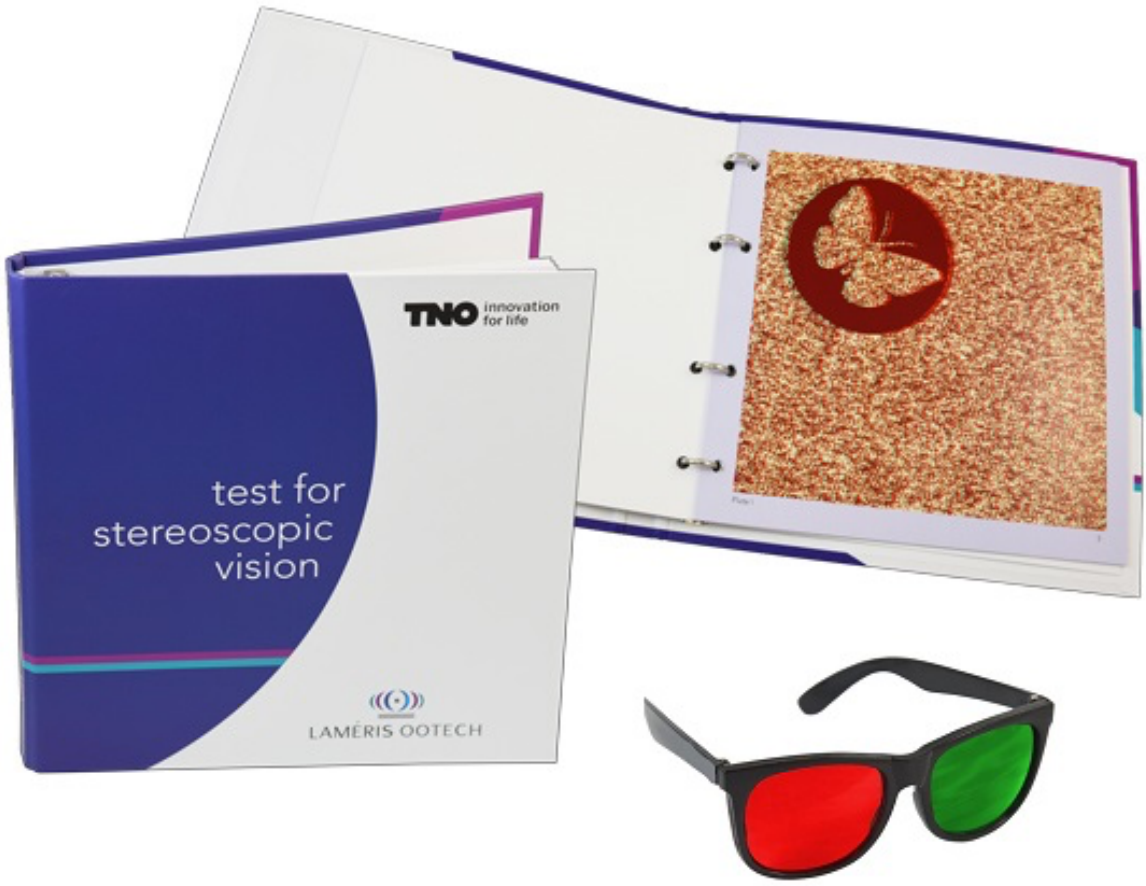
Some tests use dissociative lenses to present each eye with a separate image to achieve stereoscopic viewing conditions. The TNO Stereo Test uses red and green random dot stereograms viewed at 40cm with red and green filter glasses. This test includes screening plates and quantitate plates to detect between 480 and 15 arcsec. Figure 1.3 shows the TNO Stereo test with the butterfly screening plate, and the red and green glasses. Figure 1.4 depicts the Titmus stereo test. The Titmus stereo test uses vectograph print which creates two contour stereogram image targets polarized at 90 degrees to each other. They can be viewed with polarized filter glasses. The disparity range on the Titmus stereo test is 3000 to 40 arcsec. The Randot Stereo test, pictured in figure 1.5, uses the same vectograph format to present random dot stereograms The vectograph principle can also be used to assess distance stereopsis. Vectograph distance tests can be projected or used in conjunction with a monitor system (Lee & McIntyre, 1996).

Some tests can be viewed stereoscopically without dissociative glasses, such as the Lang Stereo test. The Lang test is based on two principles: random dots stereogram and cylindrical gratings. The test is presented on a card with thin vertical cylindrical lens elements overlaying the random dot pattern. This presentation allows each eye to view a separate image, figures formed by a pattern of disparate dots give rise to the appearance of depth when fused (Lang, 1983). The Lang Two Pencil test is used to assess gross stereopsis. It is performed by having the patient hold one pencil above their head and bring it down to touch the end of another pencil held in front of their face by the examiner, under monocular and binocular conditions. No obvious difference in performance under monocular conditions compared to binocular conditions, is indicative of a lack of binocularity. Improved performance under binocular conditions is indicative of gross stereopsis. Figure 1.6 depicts the Frisby stereo test which uses real depth by printing a pattern on one side of clear testing plates of varying thicknesses, and a circle form made up of the same pattern. On the reverse side, the circle is hidden in one of the four quadrants. This test measures threshold values between 20 and 600 arcsec by the changing plate thickness and testing distance (J. Lee & McIntyre, 1996).

A new stereopsis test called ASTEROID presented on a tablet computer uses an auto stereoscopic display, which allows disparate images to be presented separately to each eye without the need for dissociative glasses. This test uses dynamic patterns of random dot stereograms and is presented as 20 forced choice detection tasks to determine stereopsis threshold. It was shown to be a reliable, easy, and portable stereotest with higher test-retest reliability in adults compared to the pre-school randot test (Vancleef et al., 2019).

Figure 1.3

The TNO Stereo test



Note. From *JutronVision*. 2024 (https://www.jutronvision.com/product/tno-anaglyph-stereo-test/). Copyright 2023 by Jutron Vision.

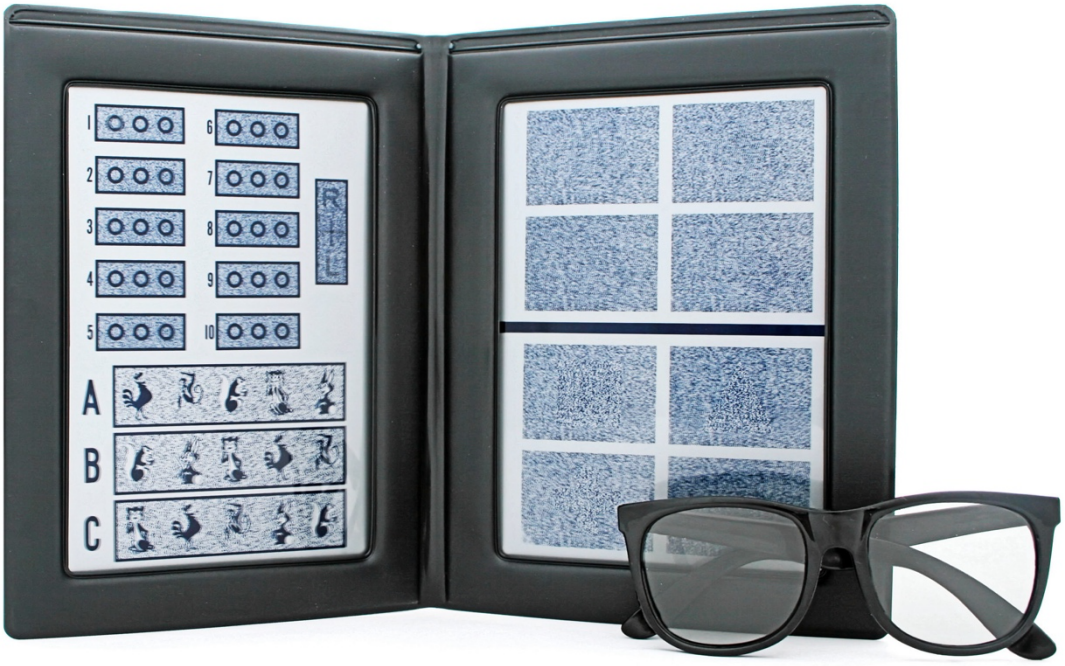
Figure 1.4

The Titmus Stereo test

Note. From *Stereo Optical*. 2024 (https://www.stereooptical.com/products/stereotests-color-tests/original-stereo-fly/). Copyright 2024 by Stereo Optical Company Inc.

Figure 1.5

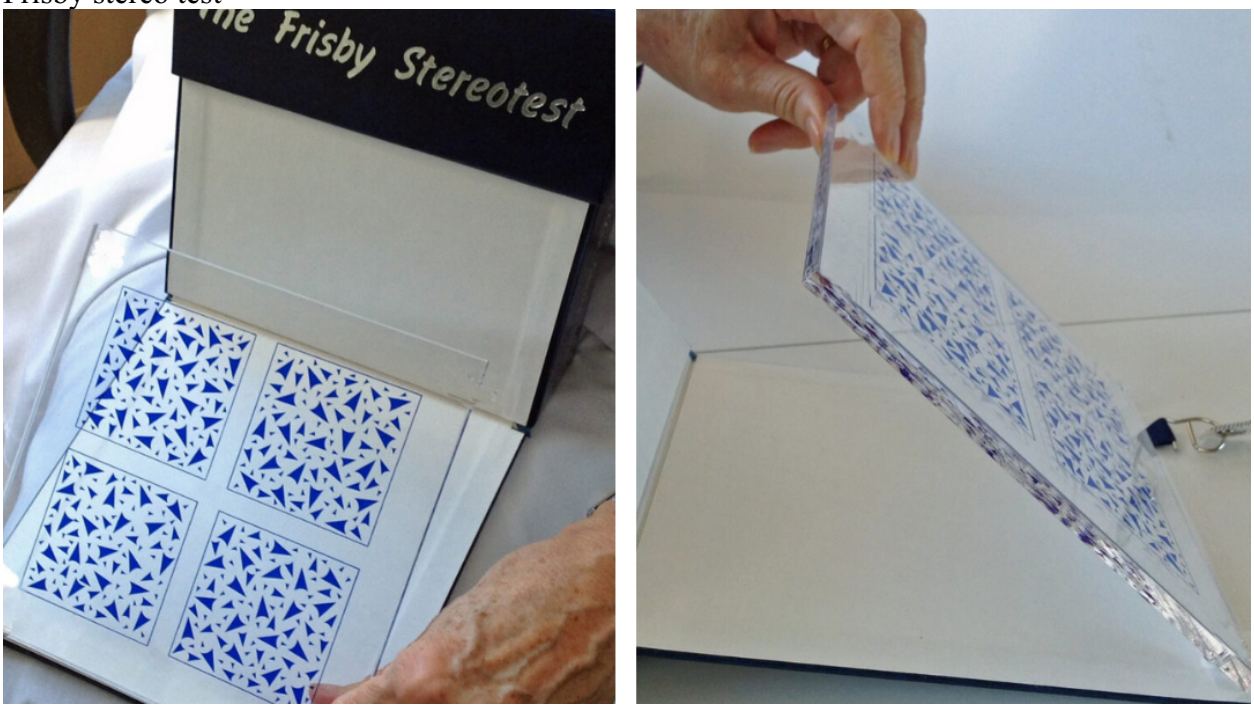
The Randot Stereo test



Note. From *Stereo Optical*. 2024 (https://www.stereooptical.com/products/stereotests-color-tests/randot/). Copyright 2024 by Stereo Optical Company Inc.

Figure 1.6

Frisby stereo test



Note. From *Frisby*. (https://frisbystereotest.co.uk/products/frisby-stereotest-near-assesment/) Copyright 2013 by Frisby Stereo test.

1.6 Professional Requirements for Stereopsis

The importance of stereopsis and binocular vision has been discussed for a number of professions including Royal Canadian Mounted Police officers, airline pilots, and surgeons (Hovis, 2021; Wright et al., 2013; Wong et al., 2010). There has been ongoing research regarding the importance of stereopsis for ophthalmic surgeons. A survey of 58 United States Ophthalmology residency program directors identified that 9% of the total residents included in their programs between 1991 and 2000 had significant issues developing surgical skills. Visual problems were only recognised as an issue in 3% of these residents. However, poor hand-eye coordination was noted in 24% of these residents, suggestive that there is possible correlation with hand-eye coordination and the development of surgical skills (Binenbaum & Volpe, 2006). In a 2007 UK survey of ophthalmologists, 80% of respondents felt that a visual standard should be required for junior doctors looking to enter ophthalmology training programs, 94% of that group believed stereoacuity standards should be set (Wong et al., 2010). In the Netherlands, achieving a perfect score on a random-dot stereopsis test has been a part of the admission requirement for prospective ophthalmology trainees for decades (Nibourg et al., 2015). While there are no formal vision requirements for entering Ophthalmology residency in Canada, the majority of programs require an eye exam for application, including an assessment of stereopsis (CaRMS, 2024).

1.7 Stereopsis and Surgical Skill Across Specialties

Laparoscopic procedures are minimally invasive procedures performed with a small camera assisted tool through a small incision in the pelvis or abdomen to allow visualization for diagnostic and therapeutic procedures. Due to the traditionally two-

dimensional viewing of laparoscopic procedures and the introduction of stereoscopic viewing, the role of stereopsis in laparoscopic procedures has been an area of interest for researchers (Sakata et al., 2016). Several studies have investigated if there is any advantage to high level stereopsis in two-dimensional viewing conditions. One study compared the performance, in terms of mean time, on a validated laparoscopic training task. This study compared performance of 14 adults, with long-term absence of stereopsis, to an age-matched control group. None of the subjects in either group had previous surgical experience. This study found that the average time required to complete the task was shorter in the normal stereopsis group, however with substantial overlap in individual times between groups (Barry et al., 2009).

Another study compared the laparoscopic skills training tasks of 91 third year medical students, 15 were found to have reduced stereopsis and 77 with normal stereopsis. Performance was recorded and was assessed by 4 independent raters. Scoring on overall performance included erratic jerking, unintentional movement, over/under grasping, knocking of pegs, or drops. Assessment of depth perception included over and under grasping (pointing past or before an object), and depth adjustments. Students with reduced stereopsis performed worse both initially, and after a practice period, when compared to their peers. Both groups however showed a similar degree of improvement from their initial attempt. This study did not control for, or document, monocular or binocular visual acuity which could impact performance under both 2D and 3D viewing conditions (Suleman et al., 2010).

In a study comparing surgically inexperienced adults with normal or absent stereopsis, all subjects required vision equivalent to 6/9.5 in both eyes for the normal

stereopsis group or at least one eye for the absent stereopsis group. Those in the absent stereo group has no measurable stereopsis or fusion on sensory testing. In this study, performance of a task in 2D laparoscopic conditions was similar between groups, whereas performance of the same task in natural viewing conditions was significantly worse in the absent stereopsis group, except when the task was performed monocularly (Bloch et al., 2015).

One study that used a virtual reality simulation of laparoscopic procedures compared performance on a variety of simulated laparoscopic tasks. In this study, stereopsis was assessed with the Lang I & II stereo test, Titmus stereo test, and TNO stereo tests. The authors in this study broadly defined impaired stereopsis as not recognising disparities of 550, 200, 40 and 15 arcsec on any of the tests, and "accurate" stereopsis was defined as recognising disparities between an arc of 1200 and 15 arcsec. This study found better, but statistically insignificant performance by the "accurate" stereopsis group on some tasks compared to the impaired stereopsis, and no significant difference in performance when performed monocularly compared to binocularly within or between groups. The possible overlap of stereopsis between the groups could have impacted the sensitivity of the findings of this study (Hoffmann et al., 2015).

The introduction of stereoscopic viewing into laparoscopic procedures has led to studies on the benefits to stereoscopic viewing on the laparoscopic procedures. One study looked at the importance of stereopsis in 2D viewing compared to stereoscopic viewing with polarized glasses among medical students and surgeons. In this study, higher level stereopsis was associated with faster completion of tasks and fewer errors in stereoscopic conditions. This study also found that the Titmus stereo test was more reliable at

predicting performance in stereoscopic conditions compared to the TNO stereo test (Gietzelt et al., 2022).

1.8 Stereopsis and Surgical Skill in Ophthalmology

In ophthalmology, there have been numerous studies on the role of stereopsis in intraocular surgeries, many of these studies have used the EYESi Ophthalmosurgical Simulator. This simulator uses binocular microscopic viewing to simulate intraocular procedures and training tasks. The first study to look at the role of stereopsis in intraocular surgery with the EYESi compared two groups of 21 patients. The normal stereopsis group had vision 20/40 or better in each eye and stereopsis of 60 arcsec or better. The absent or reduced stereopsis group had best corrected binocular vision of 20/40 or better and stereopsis of 80 arcsec or worse on the Titmus test. All participants were between the ages 10 to 75. Participants completed 2 anterior segment training modules, at the first level of difficulty tasks were repeated 3 times and once at the more complex third level. The normal stereopsis group consistently scored better across all 4 trials compared to the absent or reduced stereopsis group in terms of accuracy, efficiency, and stability. There was no significant difference in the improvement in each group between trials (Sachdeva & Traboulsi, 2011).

In a study of 70 medical students, subjects completed 3 cataract training modules: navigation, forceps, and capsulorhexis on the EYESi Ophthalmosurgical Simulator. After completing the simulated tasks their stereopsis was assessed using the TNO test. There was a correlation found between overall simulator performance and the TNO score, and for the navigation and forceps tasks with better stereopsis being associated with better performance. However, no correlation was found for the capsulorhexis module

performance and level of stereopsis. The capsulorhexis module was performed at an easier level than the other tasks (Selvander & Åsman, 2011). This study has a limited sample of subjects with reduced or absent stereopsis. The majority (70%) of the subjects scored between 30 arcsec and 60 arcsec on TNO. The investigators did not report visual acuity of the subjects and could not account for impacts of long-term training based on this study alone.

A study by Waqar and colleagues assessed the impact of acute loss of stereopsis on surgical skill. This study consists of a sample size of 30 "junior" doctors with no prior ophthalmic microsurgical experience. All participants had visual acuity of 6/6 or greater at distance and N6 or better at near. No inclusion criteria for stereopsis were stated however, the sample group had a mean stereopsis of 35 arsec measured with the Frisby test. Participants performed the 4 attempts of the forceps module task first binocularly, then with one eye occluded. This study showed a significant decrease in performance scores in the monocular condition compared to the binocular condition. However, some participants performed well under both conditions. Although this study supports that an acute loss of binocularity is associated with decreased performance on this task, it does not account for adaptations that people with longstanding absent or decreased stereopsis can acquired over time (Waqar et al., 2012).

A study by Nibourg and colleagues, in 2015, looked at the potential influence that stereoscopic depth perception has on the performance of a microscopic task. Seventy-seven medical students were grouped based on their level of stereopsis. Stereo-sufficient was defined as 240 arcsec or better and stereo-deficient was defined as stereoacuity equal to or worse than 480 arcsec. The TNO stereo test was used in this study for stereoacuity

measurement. One group of participants completed a bead stringing task using an operating microscope under stereoscopic, binocular non-stereoscopic, or monocular viewing conditions. Stereo-sufficient subjects completed the task in two of the three conditions assigned by stratified randomization, and stereo-insufficient subjects completed the task in the stereoscopic viewing condition only. A second group of subjects also completed cataract forceps training task using the EYESi Ophthalmosurgical Simulator. The bead stringing task was recorded and scored by number of errors and elapsed time, while the EYESi task was evaluated with the program software. The stereo-deficient group had longer completion times than the stereo-sufficient group in the bead string task under stereoscopic viewing, even with improved times on repeated attempts. There was no significant difference in performance between the stereo-insufficient group and the binocular non-stereoscopic viewing group, and both groups had a median time of the last three runs that were significantly worse than those of the stereo-sufficient group under stereoscopic viewing. Within the stereo-sufficient groups, performance in the stereoscopic conditions was better than both binocular non-stereoscopic and monocular conditions. However, there was no significant difference between the monocular and binocular non-stereoscopic groups. Longer test times was significantly associated with more errors, with the correlation stronger, but not significantly greater, in the stereo-deficient group. In the surgical simulator task, there was no significant difference in performance between the groups, however the stereo-deficient groups tended to have slower times. This small study suggests there is a benefit to stereopsis for efficiency of tasks completed under microscopic viewing. However, the findings of this study did not support the hypothesis that long term adaptations to absent

stereopsis over time would allow for better performance when compared to stereo-sufficient subjects in non-stereoscopic viewing conditions. This study did not look at long term training and learning effects in either group (Nibourg et al., 2015).

In a prospective, randomized study by Dutton and colleagues, the authors sought to determine whether there is a relationship between the degree of stereopsis impairment and the ability to perform a simulated microsurgical task. Twelve medical students with normal vision and stereopsis were included in this study. The examiners used a band-pass filter over the subject's non-dominant eye to create a reduction in stereoacuity levels. The Frisby stereo test was used for all stereoacuity measurements. Using this filter, partial stereopsis (150 arcsec) and absent stereopsis levels were simulated. Participants completed the cataract forceps training task using EYESi Ophthalmosurgical Simulator under normal (binocular, no filter), partial stereopsis, and absent stereopsis conditions in a randomized order. They found that time elapsed for task and number of ocular injuries were higher, on average, in the partial stereopsis group, and higher still in the absent stereopsis group. This study found a dose-dependent relationship between the level of stereopsis and scores for ocular damage and efficiency on the simulated surgical task (Dutton et al., 2020). While this study may serve as a reasonable model for acute acquired decreases in stereopsis, it did not address long standing reductions in stereopsis.

In a similar study of 39 ophthalmology residents with normal vision and stereopsis, researchers simulated anisometropia by adding cylindrical or spherical lenses between +1D and +5D power over one eye, in addition to any necessary refractive error correction. The optical lenses were used to simulate uncorrected anisometropia. The authors looked at the impact on the performance of an anterior segment navigation

exercise on the EYESi Ophthalmosurgical Simulator. This study found that artificially induced anisometropia resulted in a reduction in stereopsis when subjects were tested using the TNO and Random Dot stereo tests. The authors did not report the change in visual acuity due to the induced anisometropia. In this study a statistically significant relationship was reported between increased spherical and cylindrical power added and performance on the EYESi task, and a significant relationship with deterioration of stereopsis with increased lens power added. Stereopsis scores on both TNO and Frisby had a significant positive correlation surgical task score (Singh et al., 2021). This study did not address the impacts of longstanding anisometropia or naturally occurring anisometropia after an adaptation period.

In a study of 50 medical school students and recent graduates, with no more than 1-2 hours of previous experience using the EYESi Ophthalmosurgical Simulator in the last 12 months, subjects were asked to complete the forceps manipulation task (Forceps Level 4 module) 4 times. This study found the velocity, linear and rotational acceleration of the instrument to be independent of stereopsis. Visual acuity had no significant effect on performance, and there was no statistical significance in performance between the groups with 30, 60, or 90 arcsec on TNO. However, there was a significant difference in the surgical performance of participants with worse than 120 arcsec compared to those with 120 arcsec or better. While this study demonstrated improvement in all groups with repeated trials, the group with worse than 120 arcsec stereopsis consistently scored lowest (Burgess et al., 2021).

The literature suggests that stereopsis is associated with more efficient and accurate surgical performance in simulated intraocular surgery. EYESi

Ophthalmosurgical Simulator has allowed for a controlled and highly reproducible model to study intraocular surgery. Currently, no such model exists for strabismus surgery, however new developments of virtual and augmented reality may allow for an effective model.

1.9 Representing Depth in Virtual Reality

In virtual reality, especially when using a head mounted display, there are unique challenges to convey depth. In the headset the light is typically projected from a relatively flat surface at a fixed or uniform distance. This can cause a conflict for the visual system due the discrepancy between where light of an image is emitted and the simulated location of the image. Accommodation and convergence response may be stimulated by the near emittance of light, even when the projected images are intended to appear in the distance (Vienne et al., 2020). Some VR studies have demonstrated a tendency toward over-estimating distance of targets in head mounted display VR settings (Naceri et al., 2010).

Monocular viewing could also play a different role in virtual reality compared to real world viewing. Linear perspective depth cues have been found to be more important than texture for the perception of relative depth in VR (Yildiz et al., 2024). As well, familiar size tends to be more important than binocular cues when estimating depth in VR head mounted displays, compared to real world viewing (Rzepka et al., 2022). Motion parallax has also been shown to be important for depth perception in VR. Vergence-accommodation conflict is one challenge observed in displaying depth in VR systems due the mismatch of distances for accommodation and convergence. However, rich virtual environments have been shown to resolve this conflict (Vienne et al., 2020).

1.10 Virtual Reality in Medicine

Virtual reality surgical simulations have been an effective tool, not only for developing surgical skills, but also as a tool for studying the impact of impaired stereopsis on surgical performance. Virtual reality is a simulation of the real world based on computer generated graphics (Riener & Harders, 2012). While VR can be applied to a broad array of technological systems, the basis of VR technology includes an output displaying a sensory environment, an input to collecting data such as movements, and an interface to process this data and allow for interaction with the simulated sensory environment (Riener & Harders, 2012, pp. 1–11). Virtual technology has been a tool in multiple areas of medicine including medical education, therapeutic treatment, and surgical training (Levi, 2023; Riener & Harders, 2012).

1.11 Virtual Reality in Ophthalmology

In ophthalmology and other surgical specialties, surgical skills are developed largely through observation and hands on surgical learning within the operating room. In a 2008 survey of senior Canadian ophthalmology residents (PGY4 and PGY 5) and recent graduates, 70% were satisfied with the case volume of surgeries in the program and 82% reported that they felt comfortable performing strabismus surgeries. However, of the 40 graduated respondents the number of reported strabismus surgeries performed in residency ranged from 0 to over 50, with 17.5% of respondents with fewer than 21 reported operations (Zhou et al., 2009). Due to the inconsistency of surgical experience across programs and residents, especially within subspecialties, residents may be lacking the necessary experience and confidence to safely use these skills upon graduation. In surgical training, virtual reality has the advantage of being a safer, more cost and time

efficient method for practicing surgical skills (Riener & Harders, 2012). Virtual reality surgical simulators allow for surgical skill development in a controlled environment without risk of patient harm. In addition, these simulators have also served as a useful tool for research on surgical skills (R. Lee et al., 2020).

Virtual reality and augmented reality systems have been used for the diagnosis and treatment of strabismus and binocular vision disorders. Several studies have used extended reality systems to treat amblyopia, and new systems are being developed to use this technology to treat and assess stereopsis and strabismus (Levi, 2023). A new prototype using a virtual reality headset for the treatment of amblyopia in older children and adults has recently been described. Use of this prototype has been associated with a small, but significant improvement in stereopsis results after 8 weeks of treatment (Elhusseiny et al., 2021).

The EYESi Ophthalmosurgical Simulator is one of the most used and researched models for surgical training. This simulator consists of a high fidelity simulation of intraocular surgical procedures (R. Lee et al., 2020). It has allowed a better understanding of the role of stereopsis in surgical procedures like cataract surgery. Although there is very limited evidence to identify the level of stereopsis that is critical for surgical training, several studies have investigated the effect of stereoacuity on simulated intraocular surgery. Sachdeva and Traboulsi found significantly better performance with the EYESi Ophthalmosurgical Simulator in the control group compared to the group with reduced or absent stereoacuity (Sachdeva & Traboulsi, 2011). Nibourg and associates found that stereo-sufficient medical students completed an EYESi cataract simulator task and a bead stringing task under an operating microscope faster than those who were

stereo-deficient, however deficient stereoacuity did not prevent the group from completing either task successfully (Nibourg et al., 2015). Selvander and Åsman found a correlation with stereoacuity and performance on two of three EYESi intraocular surgery modules, indicating better performance with higher level stereoacuity in a study of 70 medical students (Selvander & Åsman, 2011). In a study focusing on performance in simulated cataract surgery by 50 medical students and medical graduates, Burgess and associates found there was no significant difference in performance on a simulator task with participants with 30, 60, and 120 arcsec, however beyond 120 arcsec there was significantly worse surgical performance. These results suggest that the presence and level of stereopsis could affect surgical performance. (Burgess et al., 2021).

1.12 Virtual Reality Strabismus Surgery Training

A small prospective study in Detroit, Michigan comparing strabismus surgery efficiency and complications between ophthalmology residents and an attending surgeon found higher rates of complications and longer operating times for residents compared to the attending physician. Another large retrospective study in Cairo, Egypt also reported statistically significant rates of perioperative complications in surgeries performed by supervised residents compared with experienced ophthalmologists (Arfeen et al., 2019; Riddering et al., 2020). Although observation and wet labs can aid with surgical exposure and training, they allow little to no objective skill assessment of residents.

While the EYESi Ophthalmosurgical Simulator and other virtual reality technologies have been developed for intraocular eye surgery, there are still no validated virtual reality simulations available for extraocular muscle surgery. Virtual reality

simulation has advantages as a training tool with the possibility of performance metrics, feedback, and objective assessment (R. Lee et al., 2020).

Current wet lab simulations for strabismus surgery include animal models such as pig or rabbit heads. In addition, bacon has been demonstrated as a possible substitute for extraocular muscles (Vagge et al., 2017; White et al., 2015). The use of animal models allows work with real tissue, but still has several limitations including, cost, availability, and anatomical similarity to humans. Non-biological models for strabismus surgery include a ball and elastic band model which have been shown to be effective at teaching basic steps of strabismus surgery compared to biologic wet lab for medical students (Adebayo et al., 2018). A high-fidelity silicone model has also been developed to learn and practice strabismus surgery. This silicone model was reported to be more realistic compared to a rabbit head model by more experienced strabismus surgeons (Jagan et al., 2020). Non-biologic models are advantageous because they can be more cost effective, and they provide an opportunity for safe and accessible unsupervised practice. Virtual reality simulations can also give the opportunity for unsupervised practice and repetition, as well as providing objective assessment and feedback to the learner. A validated virtual reality surgical model can allow for a broad range of prospective surgical research that may not be ethical or reasonable to conduct with real patients (Selvander & Åsman, 2011).

While several studies have sought to determine the effect of absent stereopsis on surgical performance, those in the field of ophthalmology are limited to looking at microscopic intra-ocular surgery. There is currently no data on the effect of absent or reduced stereoacuity in extra-ocular surgical techniques where less magnification is

needed. However, the precise level of tissue handling is still within ¼-½ mm, for example in strabismus surgery where manipulation of extra-ocular muscles and sclera are routine. Further exploration in this field could lead to knowledge that could be transferred to other surgical fields outside ophthalmology where a significant level of precision is needed.

1.13 The Purpose of the Study

The purpose of this study is to determine if longstanding absent measurable stereoacuity in strabismic individuals impacts accuracy, completion speed, and efficiency of a task simulating the insertion of a needle into the edge of a rectus muscle, an important step of strabismus surgery. The secondary aims are to determine if repetition helps performance in stereo-absent individuals to a greater extent than in stereo-normal individuals. If so, we aim to determine if accuracy of stereo-absent individuals improves to a level like that of normal subjects with normal stereopsis after repeated trials and if stereo-absent individuals demonstrate different movement patterns than stereo-normal individuals. Another aim of this research is to determine if their self-evaluation of fine motor skills of subjects with long-standing absence of stereopsis is influenced positively by their results on an objectively scored fine motor skill task.

To accomplish these aims, the present study will compare the ability of participants with reported longstanding absent stereopsis and sensory adaptation to strabismus to that of, age-matched, participants with normal stereopsis, in completing a simulated ophthalmic surgical task using a VR simulator. Our hope is to add to the body of knowledge concerning the importance of stereopsis on surgical performance, and to inform screening practices for employment of potentially sensitive activities including

training of surgeons. We also hope that our novel study method will be robust enough to be useful in further studies of the subject.

1.14 Hypotheses

For the proposed study, we hypothesize the following:

1. Individuals with absent stereoacuity will initially show worse accuracy and efficiency with more attempts at reaching, less accurate reaching movements, more head and eye movements in performing the task compared with stereo-normal individuals.

2. Individuals with absent stereoacuity who perform poorly initially will show improvements in accuracy and completion time reaching values equal to those of stereo-normal individuals with repeated trials.

3. Individuals with absent stereoacuity will report, using a pre and post task questionnaire, better performance than initially expected in the simulated surgical task, compared with stereo-normal individuals.

Chapter 2 Methodology

2.1 Research Design

This was a quasi-experimental design experiment with two groups of surgically naive adult subjects. Subjects were assigned to two groups based on their stereopsis level: normal stereopsis and absent stereopsis. The quasi-experimental design was chosen because we were unable to randomize the independent variable (presence of normal or absent stereopsis). To control for this potential study limitation, participants were age matched in an effort make the groups as homogeneous as possible.

2.2 Study Sample

The study sample consisted of two groups of healthy adults with no prior surgical experience. The two comparison groups included: one with reported long-standing absence of measurable stereopsis in the presence of a manifest strabismus or a history of strabismus; and the second group with normal stereopsis and no evidence of manifest strabismus. Subjects were selected, and age-matched, between the ages of 18 to 60. This age was selected to capture the subjects with the appropriate attention, coordination, and understanding for the task required. Moreover, subjects in this age range would represent an acceptable proxy for medical students, ophthalmology residents, and practicing ophthalmic surgeons. Age matching of participants was intended to account for development and decline of stereopsis and fine motor skills with aging (Zaroff et al., 2003). For the purposes of this study, age matching was defined as the age of any study participants +/- five years.

2.3 Sample Size

The intended sample size was a maximum sample size of 40 participants. The IWK consulting research scientist, Dr. Jill Hatchette, was consulted to determine an acceptable sample size. The sample size was based on the expected mean differences between two groups. This calculation was done with the assumption that the stereo-normal group will perform at 60% success +/- 20% over trials and that the baseline for the stereo absent group would be 50% success with a 30% success increase over trials. For an alpha of .05 and 80% power, it is estimated that 19 participants in each group (38 total participants) will be sufficient to detect performance differences.

2.4 Inclusion Criteria

All subjects were required to have normal hand coordination as evaluated neurologically by both a Finger-to-nose test and a Diadochokinetic challenge of the fingers, and a normal extraocular motility. This criterion was intended to exclude individuals with a hand or upper limb tremor or irregular eye movements that could potentially affect performance in the VR surgical simulator.

Stereo-absent group inclusion criteria:

- Manifest strabismus or reported history of manifest strabismus
- No measurable stereoacuity on the Titmus Stereo Test Fly
- Best-corrected visual acuity of 6/7.5 or better in the preferred eye and with both eyes open and at least 6/30 in the non-preferred eye

Stereo-normal group inclusion criteria:

- Stereoacuity of 40 arcsec on the Titmus Stereo Test

- Best-corrected visual acuity of 6/7.5 or better in either eye and with both eyes open, at near and at distance

Visual acuity assessment - all subjects:

- Both near (40cm) and distance stereoacuity (20 feet) was performed on all subjects. The M&S ETDRS was the acuity test for distance and the Sloan vision test was performed at near

2.5 Exclusion Criteria

All subjects:

- Any reported diplopia
- Any tremor that will impede the ability to complete the task.
- Limited extraocular motility of any cause
- Inability to comprehend or physically complete the experimental task.
- Any history of previous or ongoing ocular pathology other than strabismus
- Manifest or latent nystagmus
- Neurological conditions affecting hand coordination such as Parkinson's Disease, Huntington's Disease, Chorea, Cerebellar Ataxia, or Multiple Sclerosis
- Prior surgical experience
- Lack of ability to self-consent

2.6 Recruitment

The stereo-absent subjects were recruited from patients seen clinics at the IWK Health Eye Clinic, Halifax, Nova Scotia. Eligible participants were identified either at or before the time of their appointment by a staff Orthoptist or a Pediatric Ophthalmologist.

Any potential subjects identified by the staff clinician were asked if they would be interested in speaking with the research examiner to learn more about the study.

The stereo-normal subjects were volunteers recruited through verbal networking. This group consisted of volunteers recruited amongst the staff and student body of the IWK and local university institutions. The research examiner approached interested individuals to explain the project and preliminary consent. A screening interview was conducted with identified candidates who are interested in the study to find obvious exclusion criteria (e.g., history of eye disease or surgery, history of neurological disease, admitted tremor etc.). Eligible subjects received a detailed call to carry out and to review details of the study and the consent document. A study visit was scheduled to carry out the signing of the consent form after further discussions and the opportunity for questions from the participant. Once informed consent was obtained the screening tests and experimental procedures were conducted.

2.7 Screening and Group Assignment

All screening tests were performed following a confirmatory self-assessment questionnaire for inclusion and exclusion criteria (Appendix A). The Titmus Stereo test and an E-ETDRS (M&S) Visual Acuity Chart are to be used for stereopsis and monocular and binocular Visual Acuity measurements (at near and distance) respectively. Participants were assessed for upper limb tremor by demonstrating two maneuvers (forward horizontal reach posture, and finger-nose-finger testing) and one drawing task (Archimedes spirals) from the TRG ESSENTIAL TREMOR RATING ASSESSMENT SCALE (TETRAS©) V 3.1. All the above assessments were administered, scored, and recorded by the research examiner, a Certified Orthoptist and Certified Ophthalmic

Medical Technologist. Participants also completed the Waterloo handedness questionnaire (Appendix B).

Following the screening procedure, participants reviewed their history with the investigator and received a clinical examination of extraocular eye movements to assess for any abnormal extraocular motility. Based on the results of the examination and interview, the participants were assigned to the appropriate group as applicable.

2.8 Survey of Self-Perception of Limitations

Both subject groups were given a questionnaire (Appendix C) to examine their perceived limitations of fine motor skills (e.g. the surgical task of the experiment, sewing, etc.) and to document if the subjects felt that there is a relationship between the presence or absence of stereopsis and their confidence in their fine motor skills. The questionnaire also included a self-assessment of their ability to perform fine motor tasks such as the surgical experiment, sewing, fine woodworking, etc., and whether this assessment was related to the presence or absence of stereopsis.

2.9 Virtual Reality Procedure

The present study used a surgical simulation program called the Rectus Inc. developed by Electric Puppets for use on the HTC VIVE Pro virtual reality system. The program used a PC computer and the HTC VIVE Pro virtual reality head mounted display and controllers, pictured in figure 2.1.

Figure 2.1

HTC VIVE Pro virtual reality system

Note. From *HTC*. (https://www.vive.com/sea/product/vive-pro/). Copyright 2024 by HTC Corporation.

Instructions were given verbally to the participants; using a model of the extraocular muscle surgery, they were be shown the task to perform later in Virtual Reality (VR) for the experiment (Appendix D). This was to familiarize the subject in a real-world environment before entering the VR environment for the simulated task. There was no training before the experiment, nor was there any coaching throughout the experimental task. The hand movements through the linked data from the wand controllers represented as the surgical instruments in the simulation.

Once the subject was seated with the virtual reality headset on and both wrists were rested comfortably as if ready for strabismus surgery, they were given two paddles which were represented in the VR image as the muscle hook in the non-dominant hand and a needle driver loaded with a 6-0 suture in the dominant hand. In the VR image, a muscle hook is holding a 0.75mm thick extraocular muscle in place viewed only from face on by the subject without an available side view, as to require a precise evaluation of the position in three-dimensional space. The latter image was artificially stabilized to help the subject concentrate on the only task to be monitored: contacting the needle in the edge of the muscle that is 0.75mm thick.

Trail 1: In the first trial, there were 4 attempts with 30 seconds in between each attempt. Each attempt will be limited to 30 seconds before the system froze. The VR image was blocked from the effect of head movements to prevent the use of any parallax clues. Participants were instructed to insert the tip of the needle within the 0.75mm thick edge of the muscle using one continuous motion. During the 30 second break following each attempt, subjects were instructed to place their hands in a resting position of their choice without holding the wands. This was intended to separate the experience and

timing of each attempt and facilitate both a positive psychological environment for the subjects who fail initially.

Trial 2: In the second trial, head movements were represented in the movements of the VR image to allow the use of motion parallax depth cues. The subjects were allowed to use any head movements to help accomplish the task. As with the first trial, there was 4 attempts with 30 seconds in between each attempt. Each attempt was limited to 30 seconds before the system froze.

All trials were monitored by the investigator in the same room as the subject, with the subject's view of the experiment reproduced on a conventional 2-D screen linked to the VR computer from where the experiments are controlled and monitored, and where the data is anonymously collected for analysis.

2.10 Clinical Measures

Performance of the surgical task would be quantified in terms of accuracy and efficiency. Accuracy would be measured as radial error and successful attempts. Accuracy would be measured as the number of attempts that are successful in hitting the target out of the total number of attempts.

Efficiency would be measured as path length and completion speed. This would be computed as the length in millimeters of the spatial path taken by the virtual needle-driver tip from the start to the end of the task, based on the principle that a shorter path length requires less movement and energy. Completion speed would be measured by the speed of the movement in doing the task to completion (whether successful or not) in centimeters (cm) per second. Changes in the speed of movements along the path within each attempt would be subjectively analysed.

Head movement would be recorded with the VR system where the number of tilts, turns, (in degrees) or lateral translations (in cm) would be recorded as well as the investigator's direct observation of the task performance. This would take into consideration the direction(s): rotation, tilt, translational; estimated number: none, few, many; and speed: slow, rapid. The investigator would not be masked as to which group the subject belongs.

2.11 Ethical Considerations

Approval for this study was obtained from the IWK Health Research Ethics Board (REB) (Appendix E). Free and informed consent for participation was obtained by the primary investigator after subjects had an opportunity to review the consent form (Appendix F) and ask any questions concerning the study. Subjects were enrolled into the study following their written authorization. Subjects had the ability to withdraw from the study at any time and were assured that their choice to participate would not affect their care at IWK Health.

Benefits of participation in this study included giving participants an idea of what it feels like to do eye surgery. Participants interested in ophthalmology were given an opportunity to explore this interest in a safe fully virtual setting. The knowledge gained from this study will help better understand how people with no measurable stereopsis function for certain fine motor tasks.

Participating in this study will give an idea to naive participants what it feels like to perform a simulated virtual reality eye surgery. If a participant is interested in becoming an ophthalmologist, this will help to further explore this interest. Knowledge gained from this study will help better understand how people with reduced and no

stereopsis perform and adapt when completing fine motor tasks. This study may also help to determine if there is a need to specify a certain level of stereopsis requirements for admission to ophthalmology residency program.

Potential harms to participants included the risk of disorientation and small risk of nausea sometimes associated with virtual reality. All the eye tests for this research project have been demonstrated to be safe and are used routinely in ophthalmic clinical settings.

2.12 Statistical Analyses

Differences between the stereo-normal and stereo-absent groups were compared with independent sample t-tests and Mann Whitney U-tests. To assess accuracy and efficiency, task performance variables (radial error, total path length, and completion speed) were analyzed using multivariate analysis of variance (MANOVA) with group (normal versus absent stereopsis) and the attempt identification number (1-4) as the between and within subjects' variables, respectively. Similarly, differences in saccade metrics (total saccades, average saccade amplitude, average saccade velocity) were analyzed using group x trial MANOVA.

Chapter 3 Results

3.1 Summary of Results

The initial trial of the experiment demonstrated several design and technological obstacles that prevented the collection of meaningful data to support or reject our hypothesis. Technological failures prevented further trials with the existing equipment and program. The following results are limited to the feedback collected from the subject and examiner following the initial attempt of the experiment. Verbal consent from the subject was given for the inclusion of their feedback in this manuscript.

3.2 Subject feedback

The subject reported that would have preferred if there was an indication such as a colour change for a success as they had difficulty knowing if contact was made with the muscle/eye especially on the head detached view. They described that they felt that they "kept pushing" past the edge of the muscle and were unsure when contact was made. The lack of ability to see the timer resulted in the subject being unable to determine when the attempt has ended. This lack of ability to determine if the timer had expired, thus concluding that attempt, was especially difficult in this head-detached view, therefore the subject's perception of either a successful or failure attempt was unclear. Contrary to our expectations, the subject found the first trial with the head attached view (free of motion parallax cues) to be easier, citing the clearer image of the task as the reason. As well, while they found the movements of the needle driver corresponded to the hand movements in space in the first trial (head-attached), in the head-detached-view where the hand was in the VR simulation did not correspond to where the hand was in space.

Unexpected challenges noted in both trials included difficulty locating the start boxes and timer, which caused a delay to move into the correct position for the surgical

task and unclear start and end times. The subject was unsure if they were looking through or over the loupes when asked. The examiner could not see the loupes in the monitor view.

3.3 Examiner feedback

The examiner was unable to reliably observe and record head movements of the subject and the monitor simultaneously. The scoring reported on the monitor registered some attempts as a success and a sclera/hit or under muscle hit, and without playback or recording of attempts the score could not be reliably determined by observation alone. The elapsed time of each attempt disappeared at the end of the attempt, which prevented the recording of timings of each attempt by observation alone. Performance could not be viewed through the monitor as the surgical area was not visible.

3.4 Conclusions from current study

Due to the VR technology being incompatible with updated computer software, we were unable to continue development using the current VR system and technology. As a result, we were unable to reject or support our hypotheses regarding the role is stereopsis in strabismus surgery. However, as the next chapter will discuss, this study did provide insights and considerations important for future development and research in the field of surgical simulations for strabismus surgery.

Chapter 4 Findings and Development

4.1 Limitations of current model

Our study failed to produce data necessary to address our hypothesis, however, this study did bring to light several limitations with the current VR strabismus surgery model, as well as considerations for further development of a strabismus surgery model. This chapter will discuss the obstacles that prevented this study from collecting the data required to investigate the importance of stereoacuity in a virtual reality model of strabismus surgery. The primary factors that impeded the success of this study can be organized in terms program design, technological limitations, and experimental design as shown in table 1. This chapter will discuss these obstacles and proposed solutions for further development.

Program Design	Technological Limitations	Experimental Design
Adjustable setup Graphics/Image Quality Timer and scoreboard 2D Monitor view	Eye movement recording Hand movement recording Radial error, total path length, and completion speed of each attempt not recorded Playback Size and weight of VR headset and controllers	Recruitment Validation of surgical simulator

Table 1. *Summary of the factors that prevented success in our experiment, discussed in sections 4.2 (Program Design), 4.3 (Technological Limitations), and 4.4 (Experimental Design).*

4.2 Program Design

The strabismus surgery simulation program used in this study was a novel program developed for the purpose of our research questions. As this program had not been used before for experimental or educational purposes, there were some findings of limitations and potential sources of error during the experimental set up and attempted trial. These limitations contributed to cessation of recruitment and data collection. Some features on the user interface such as the loupes, needle, and table height were adjustable using sliding scales. While some features such as interpupillary distance and height of the virtual operating table would require adjustments between subjects, unnecessary

customization between trials or users could introduce confounding variables and sources of error. Without standardized numerical values for the subject and instrumentation set up, there was a possibility of inconsistency between trials and difficulty ensuring reasonable values for each subject as they were selected based solely on the subjective preference of the subject. Loupe convergence, magnification, orientation, and size were also adjustable without a numerical value attached which could allow for unintentional variation between subjects and/or trials. These values should remain the same for all subjects and trials. Assigning fixed values could eliminate this potential source of error in experiments and create a more user-friendly interface which would be beneficial especially if the program is expanded upon for use in educational and training purposes. Similarly, the needle orientation was adjustable in the user settings, rather than being adjustable with hand positioning or remaining fixed at the appropriate orientation for the assigned task. It is important to limit the settings that can be manipulated between users and trials, and for any fixed settings to be at a constant value or orientation consistent with what is determined to be realistic by an experienced strabismus surgeon or surgeons.

In the attempted first trial of the experiment, there were discrepancies reported by the subject in the image quality in the head attached vs detached view. Although we could not determine the cause of this, it is possible that it was a limitation of the technology used. A faster VR display system with more frames per second could allow for more consistent visuals and less blur when the images are responding to head movements of the subject. In the current version, there is the possibility that any advantage to motion parallax could have been distorted by the perceived blur by the subject. The program should also be changed to allow for a better view and possibly a

"stationary" view of the timer and score board, so head movements are not required to visualize this information through the headset and 2D monitor.

4.3 Technological Limitations

Future developments of a strabismus surgery simulator will require an updated program using compatible technology to address the research questions proposed for this study. Due to the functional limitations of the hardware and program used for this experiment, repeated trials were not possible following requisite operating system updates. The hardware used in this study also had limitations in terms of the capabilities for data collection and analysis. The VIVE Pro VR System used in this study did not have the capacity for eye tracking, or hand tracking. While the experiment could still have meaningful results without this data, the capacity for eye movement recording would be necessary to evaluate differences in eye movements between subjects with and without stereopsis. Tracking of the controllers with the VIVE Pro VR System instead of the hands is feasible however, technology with the capacity to track the real hand movements could allow for the use of more realistic proxies for surgical tools in terms of size, shape, and weight and give a more realistic surgical experience. A limitation of the VIVE Pro VR System was the size and weight of the controllers and headset. Newer technology such as the Meta Quest 3 VR Headset, and the Apple Vision Pro may allow for a more realistic and comfortable experience and the use of augmented reality to combine physical models with virtual guidance and analysis.

4.4 Experimental Design

Limitations of the proposed experimental design included a limited sample size due to the small adult patient population at IWK Health. A small patient population pool

as well as challenges with recruitment of stereo absent participants due to the strict inclusion and exclusion criteria and the infrequency of adult patients in the clinic, in addition to limited recruitment strategies. A larger sample size could be made more feasible with a multi-centre study, a longer recruitment period, and recruitment strategies such as posters or brochures. Additionally, including a group of subjects with reduced stereopsis, not just absent stereopsis, could allow for further analysis and possibly more generalizable results.

A major limitation of this study was the use of a novel strabismus surgery simulation. As this was the first study using this program, there were no prior studies to establish validity of this program as a model for strabismus surgery. The novel nature of this program likely contributed to the unforeseen program and technological limitations as it had not had any prior use in either a research or educational setting. Had this experiment been successful in data collection, any findings would have been limited due to the unestablished validity of the program as a proxy for real strabismus surgery. In addition to necessary updates to the surgical simulation program and technology, a thorough validation study would be recommended preceding further investigations using this model to examine the role of stereopsis in strabismus surgery.

Chapter 5 Discussion

5.1 Findings and Comparative Literature

The role of stereopsis in surgical performance has been studied across several surgical specialties and procedures. There have been many studies on the role of stereopsis in simulated surgery, most numerously in the fields of laparoscopic surgery, ophthalmic surgery, and dental procedures. To our knowledge, there are no previous studies on the role of stereopsis in strabismus surgery, as this is a procedure that is unique in terms of the surgeon's viewing conditions compared to the intraocular surgeries studied.

In laparoscopic procedures performed that use 2D viewing of the surgical site there is limited and inconsistent evidence to suggest that high level stereopsis provides an advantage for performance in simulated laparoscopic tasks (Barry et al., 2009; Suleman et al., 2010; Bloch et al., 2015; Hoffmann et al., 2015). However, with polarized lenses and 3D laparoscopic viewing, good stereopsis is a significant predictor of faster and more accurate performance of a laparoscopic training task (Gietzelt et al., 2022).

In ophthalmology, there have been numerous studies on the role of stereopsis in intraocular surgeries. Previous studies have generally supported that stereopsis is beneficial for accuracy and efficiency in most intraocular surgery modules on the EYESi Ophthalmosurgical Simulator (Selvander & Åsman, 2011). Although hypothesized, there is no evidence that long term absence of stereopsis has adaptations compared to acute loss of stereopsis (Nibourg et al., 2015). While some studies suggest the relationship between surgical skill and stereopsis is dose dependant, other studies have suggested that stereopsis only tends to have a significant impact on surgical skill when stereoacuity

levels are 120 arsec or worse (Dutton et al., 2020). Despite numerous studies on the role of stereopsis in simulated intraocular surgeries, there is limited understanding on the impacts of long-term training on surgical skill when stereopsis is reduced or absent. There have also been no studies known on the role of stereopsis in extraocular surgeries such as strabismus surgery.

This study was unable to gather data to address our research questions regarding the importance of stereopsis in strabismus surgery using a virtual reality surgical model. With this said, the feedback and observations from the experiment provided insights and important considerations for the development of an effective surgical simulation model. While our findings were limited, this study was the first to use a virtual reality model of strabismus surgery, and the first study to with the goal of investigating the importance of stereopsis for performing strabismus surgery.

5.2 The Importance of a Strabismus Surgery Simulation

A validated model for researching and practicing strabismus surgery skills could have benefits beyond the scope of this study. Several studies have shown improved surgical outcomes associated with access to surgical simulation. A UK study investigated how using the EYESi Ophthalmosurgical Simulator virtual reality training modules impacted first-and second-year trainees' cataract surgical complication statistics. They reported a 38% decrease from 4.2% in 2009 to 2.6% in 2015 for surgeons with access, compared to a 3% reduction from 2.9% to 2.8% for surgeons without access to an EYESi (Ferris et al., 2020). One study utilized data that was collected by the Accreditation Council for Graduate Medical Education (ACGME). The ACGME is responsible for accrediting all graduate medical training programs for physicians in the United States.

This study looked at the type of surgical procedures ophthalmology residents annually logged over a 10-year period (2010-2019). They found there was a decline in the total number of strabismus procedures performed during residency, with a decrease of 26% between the 2010 and 2019 academic years. Although other sub-specialties also showed a decline in the amount of surgeries residents assisted, strabismus was the only sub-specialty to show a significant decline in the number of procedures performed as the primary surgeon (Oke et al., 2022). As resident exposure to specialities can influence their choice to pursue a fellowship, increased exposure to strabismus surgery, outside of the operating room, may encourage interest in the specialty (Simon et al., 2007). A validated surgical simulation for strabismus surgery may have benefits for patient safety and surgical outcomes, as well as residents' exposure to strabismus and pediatric ophthalmology.

5.3 Surgical Instrumentation Magnification and Depth Perception

Strabismus surgery is typically performed using telescopic loupes at a lower magnification than intraocular surgeries, which are typically performed with a binocular surgical microscope (DeRespinis et al., 2018). The uncertainly on how instrumentation magnification affects stereoacuity during surgery was the catalyst for a study by Du et al (2001). This study looked at how instrument magnification used during ocular surgery affected depth perception. Twenty-one subjects (10 were clinical ophthalmologists, and 11 non-ophthalmologists) with reported normal near visual acuity and stereoacuity were included in this study. The error scores during testing under three viewing conditions; unmagnified; with a 4x loupes (450 mm focal length); and with a 16x operating microscope, were analysed. The authors found that stereoacuity is better for all clinicians

under natural viewing conditions compared to both the 4x magnification loupes and the 16x magnification operating microscope. The higher magnification viewing conditions were associated with worse stereopsis scores (Du et al., 2001). As strabismus surgery is typically performed using low magnification loupes, stereopsis may play a more important role than in higher magnification or 2D laparoscopic procedures.

In Dentistry, low power magnification loupes are routinely worn for procedures. The importance of stereopsis has been demonstrated in simulated dental drilling procedures using an augmented reality simulator. The Moog Simodent dental trainer utilizes polarized glasses with loupe attachments to view the simulated task on a monitor at a more realistic working distance, and provides tactile and haptic feedback (Al-Saud et al., 2017). Due to the similar optical magnification used in dental procedures, dental simulators may be a practical model for developing an effective strabismus surgery simulator.

5.4 Future Directions

To address the major limitations of this study and build the necessary foundation for future research on the role of stereopsis in strabismus surgery, future research should focus on developing a functional model, and establishing validity. The use of augmented reality may allow for the incorporation of physical models of strabismus with the educational and analytical benefits of virtual reality.

5.5 Validation

To explore the role of stereopsis in strabismus surgery using a virtual reality model, it is important that the program used is validated as a reliable proxy for strabismus surgery. We suggest future studies should further develop and determine the reliability

and validity of a VR simulation of a strabismus surgery task as a model for the practice and study of strabismus surgery. The Messick validity framework is the current standard accepted by American Educational Research Association, American Psychological Association, and National Council on Measurement in Education. This Framework consists of five different sources of validity evidence: content, response process, internal structure, relations with other variables, and consequences of the assessment or test (Borgersen et al., 2018; Messick, 1989). To assess the validity of the current program we recommend a future study to assess the validity of the program with consideration for content, response process, internal structure, and relations with other variables as outlined in the Messick Validity Framework.

To accomplish these aims, we propose a future study recruiting from staff and fellow ophthalmologists, ophthalmology residents, and medical students to complete two sessions with the virtual reality simulation. Each session would include 10 attempts at the surgical task. After completing both sessions, experienced strabismus surgeons will complete a questionnaire about how well the simulation reflects the real surgical task and what could be changed or improved.

The proposed validation study would address the Messick Validity Framework in terms of content validity, response process, internal structure, and the relation to other variables as described in the validation of ophthalmology simulation training tools by Lee and colleagues (2020). The content validity can be addressed using an anonymous questionnaire given to experienced strabismus surgeons to evaluate the relevance of the surgical simulation, and how representative it is of strabismus surgery. Response process can be addressed by having standardization in the set up and instruction with a written

script, a video demonstration of the set up and surgical task, and standard data collection of performance efficiency and accuracy will be collected using the empirical data from the surgical simulator program. Observational data will be collected by the same investigator for all subjects (Jaud et al., 2021). Internal structure can be addressed by each subject repeating the surgical task after a set break, the internal consistency can be analyzed using Cronbach's alpha. The relation of other variables could compare the number of surgeries performed with the performance of the task, with a positive relationship using independent sample t-test indicating real surgical experiences is associated with better performance of simulated surgery.

The consequences of the assessment could be examined in future studies to determine what is the standard for successful performance and what impact this assessment or simulation has on surgical outcomes when used during surgical training.

5.6 Augmented Reality

Augmented reality allows for virtual reality immersed with the real world. Some technological limitations faced in the current study could be addressed using newer extended reality systems such as the Apple Vision Pro that allow for augmented reality (Waisberg et al., 2024). Augmented reality models could incorporate more realistic surgical tools and the possibility of combining virtual reality performance data and feedback with a physical model. Other potential advantageous features such as eye tracking and hand tracking are available on other augmented reality systems. An updated operating system would allow for modifications to the current program for the experiment to ensure appropriate data collection and consistent experimental set up.

As strabismus surgery requires handling of small tissues on the eye's surface, tactile feedback may play a different role than in intraocular surgeries performed within a smaller enclosed area. An augmented reality simulator could have the potential combine high fidelity tactile models with superimposed graphics and other visual information and data to create an effective training and research tool.

5.7 Conclusions

Despite the lack of empirical data produced by this study, the incomplete initial trial highlighted significant limitations of the current program and technology. This experiment was limited due to the experimental design, program design, and technological limitations. These significant limitations indicated the need for the further development of an effective surgical simulator to model the intended steps of strabismus surgery to revisit our research questions. It is also imperative to complete robust validation of the novel program to draw meaningful comparisons or conclusions about real strabismus surgery from this model.

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Appendices

Appendix A

Self-Questionnaire

If you answer **"YES"** to any one of the following questions, please check the "yes" box at the bottom of the page. Unfortunately, this will also mean you are *not* eligible to participate in this study.

Note: To protect your privacy, you do not need to indicate which of the questions you answered "yes".

1- Do you currently experience double vision (diplopia)?
2- Do you have a neurological conditions affecting hand coordination such as Parkinson's Disease, Huntington's Chorea, Cerebellar Ataxia, or Multiple Sclerosis or any tremor that would impede your ability to complete fine task?
3- Do you have limited movement of your eyes, due to any cause?
4- Any history of previous or ongoing eye disease/condition other than strabismus?
5- Manifest or latent nystagmus (jiggling or shaking of the eyeballs)?
6- Do you think you have difficulty understanding, or will be unable to physically complete the experimental task?
7- Do you have any experience in performing surgery?

☐ YES TO ONE OR MORE OF THE QUESTIONS ABOVE

Appendix B

Waterloo Handedness Questionnaire

Please indicate your hand preference for the following activities by circling the appropriate response:
*If you always (i.e. 95% or more of the time) use one hand to perform the described activity, circle **RA or LA** (for right always or left always). If you usually (i.e. about 75% of the time) use one hand, circle **RU or LU**, as appropriate. If you use both hands equally often, circle **EQ**.*

1. Which hand would you use to spin a top? .....LA LU EQ RU RA
2. With which hand would you hold a paintbrush to paint a wall? .....LA LU EQ RU RA
3. Which hand would you use to pick up a book? .....LA LU EQ RU RA
4. With which hand would you use a spoon to eat soup? .....LA LU EQ RU RA
5. Which hand would you use to flip pancakes? .....LA LU EQ RU RA
6. Which hand would you use to pick up a piece of paper? .....LA LU EQ RU RA
7. Which hand would you use to draw a picture? .....LA LU EQ RU RA
8. Which hand would you use to insert and turn a key in a lock?.....LA LU EQ RU RA
9. Which hand would you use to insert a plug into an electrical outlet? .....LA LU EQ RU RA
10. Which hand would you use to throw a ball?.....LA LU EQ RU RA
11. In which hand would you hold a needle while sewing? .....LA LU EQ RU RA
12. Which hand would you use to turn on a light switch? .....LA LU EQ RU RA
13. With which hand would you use the eraser at the end of a pencil?.....LA LU EQ RU RA
14. Which hand would you use to saw a piece of wood with a hand saw? .....LA LU EQ RU RA
15. Which hand would you use to open a drawer?.....LA LU EQ RU RA
16. Which hand would you turn a doorknob with?.....LA LU EQ RU RA
17. Which hand would you use to hammer a nail?.....LA LU EQ RU RA
18. With which hand would you use a pair of tweezers?.....LA LU EQ RU RA
19. Which hand do you use for writing? .....LA LU EQ RU RA
20. Which hand would you turn the dial of a combination lock with? .....LA LU EQ RU RA

Appendix C

Secondary Screening Survey and Examination Data Collection Form

Survey

Any report of suboptimal vision or amblyopia:

- Do you see equally with each of your eyes? YES ☐ NO ☐ UNSURE ☐

  If not, which eye doesn't see well? _____

  - Since when? _____
  - Do you know why? _____

- Did you have to patch or put drops in your eyes as a child for the treatment of amblyopia? YES ☐ NO ☐ UNSURE ☐

  If yes, between what ages? _____

- Do you/have you ever worn Glasses/Contact Lenses YES ☐ NO ☐ UNSURE ☐

  If yes, when? _____

- Did you have Lasik or Laser Eye surgery? YES ☐ NO ☐ UNSURE ☐

- Have you ever had any type of eye surgery? YES ☐ NO ☐ UNSURE ☐

- Have you ever had an eye disease or accident that affected your vision?

  YES ☐ NO ☐ UNSURE ☐

  - If yes, when? _____ *(yy/mm/dd)*
  - Which disease/type of accident? _____

Any reported strabismus or previous strabismus:

- Do you have or ever had an eye turn? YES ☐ NO ☐ UNSURE ☐

- Do you experience double vision? YES ☐ NO ☐ UNSURE ☐

- Did you have an eye muscle surgery? YES ☐ NO ☐ UNSURE ☐

  - If yes: Which eye? _____

Survey, cont'd

Any known Present or previous eye or neuro-ophthalmological disease

YES ☐ NO ☐ UNSURE ☐

- If yes: nature/diagnosis of condition: _____

To characterize life experience of stereopsis:

- Do you feel 3D vision was ever an issue for you in life in general?

  YES ☐ NO ☐ UNSURE ☐

  What is your job/occupation? _____

- Do you have visual demanding tasks to perform at your job? YES ☐ NO ☐
- Have you ever had to perform an eye exam for a job interview? YES ☐ NO ☐
  - If yes: What was the job? _____
  - What result did you get? _____
- Are you able to appreciate 3D movies? YES ☐ NO ☐
- Do you experience motion sickness ? YES ☐ NO ☐

Examination Data

Monocular corrected visual acuity (distance and near) E-ETDRS distance, Sloan at Near

- Distance RE _____ LE _____
- Near RE _____ LE _____

Noteto examiner: try to improve distance VA with P.H./S.L. if worse than 6/7.5

- Presence of amblyopia YES ☐ NO ☐
- Type of amblyopia: Strabismic ☐ Anisometropic ☐ Mixed ☐
- Refraction measured (auto-refraction) or corrected by glasses
  - RE: _____
  - LE: _____
- Presence of strabismus: YES ☐ NO ☐
  - If yes: type and size (in prism diopters) at distance (6meters): (X, X(T), XT, E,E(T) ET, H, H(T), size HT (or combination): _____
  - If yes: type and size (in prism diopters) at near (1/3m) : (X, X(T), XT, E, E(T), ET, H, H(T) or HT (or combination): _____
- Stereopsis (cc when appropriate)
  - At near Titmus(40cm): _____
- Presence of gross peripheral binocularity (Worth 4 dot) YES ☐ NO ☐
- Record which eye was suppressing: _____
- Presence of Tremor on

1. Forward outstretched posture YES ☐ NO ☐
2. Finger Nose Finger Motion YES ☐ NO ☐
3. Archimedes spiral task YES ☐ NO ☐

Examination Data, cont'd

Question to the subject after the experiments:

"After the completion of your surgical simulation experience, how did you feel your performance in the simulated surgical task was compared to your expectations?"

BETTER ☐ WORSE ☐ SAME ☐

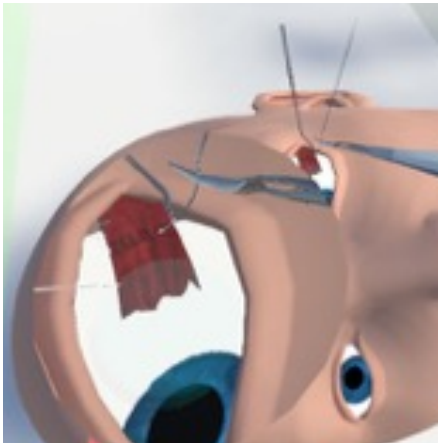
Appendix D

Experimental Procedures

- Instructions will be given verbally to the participants; using a plastic model of the extraocular muscle surgery, they will be shown the single task to perform later in Virtual Reality (VR) for the experiment This serves to familiarize the subject in a real-world environment before entering the VR environment for the measured tasks. An instructional video will be shown of the actual VR images and task with the ability to invert the images for right or left handedness preference. There will be no training before the experiment, nor will there be any coaching throughout the experimental task. An electronic virtual environment is used for this experiment because it not only allows a precise link between the totally controlled dimensions and visual conditions of the task performed but also allows the linkage of the components of the created images the eye positions (movements) of the subjects by infra-red corneal reflex positioning monitors that are part of the VR headset. We can also monitor the subject's hand movements through electronically linked "wands" used as avatars of the surgical instruments.
- With the VR headset on, both wrists comfortably rested as if ready for strabismus surgery, the seated subjects will be given a wand which is reflected in the VR image as a needle driver loaded with a 6-0 suture and its needle (right hand, or opposite for left-handed individuals). A muscle hook will appear to be holding an extraocular muscle 0.75mm thick in place and will be visualized face on by the subject without the ability to see it from the side, hence requiring a precise evaluation of its position in a 3D space. The VR image is pictured below. The latter image will be artificially stabilized to help the subject concentrate on the only task to be monitored: the threading of the needle in the edge of a muscle that is 0.75mm thick. With a successful thread, the muscle changes color to indicate a successful attempt.
- Trail 1: In the first trial, there will be 4 attempts with 30 seconds in between each attempt. Each attempt will be limited to 30 seconds before the system freezes. The VR image will be blocked from the effect of head movements therefore preventing the use of any parallax clues. Participants are instructed to insert the tip of the needle within the 0.75mm thick edge of the muscle using one continuous motion. During the 30 second break following each attempt, subjects will place their hands in a resting position of their choice without holding the wands. This will facilitate both a positive psychological environment for the subjects who fail initially, and the possibility of the subjects to become more versatile (successful) with the task. This latter training will be included in our analysis.
- Trial 2: Following the initial pure stereoacuity trial, there will be a second trial where all participants will be allowed to use the benefit of head movements to create parallax views of the target for 4 more attempts to complete the task. The subjects will be free to use whatever head movements they wish to use to help accomplish their task. The attempts will be of same duration and with the same rest periods. We will examine the strategies used by both groups and determine whether they differ. For example, we

expect the stereo-absent group to exploit strategies to enhance monocular cues such as motion parallax to accomplish their tasks, more than the stereo-normal group.

- Although tremors and barriers to completing the task will be screened for prior to enrollment in the study, the experimenter will monitor the subjects' performance during the experiment for any obvious tremors or other barriers in completing the task such as excess frustration, for example. These cases will be earmarked accordingly, and additional subjects tested to allow completion of the data set.
- All trials are monitored by the examiner who is in the same room as the subject, having the subject's view of the experiment reproduced on a conventional 2-D screen linked to the VR computer from where the experiments are controlled and monitored, and where the data is anonymously collected for analysis. Successful attempts can be identified by the investigator by a color change in the VR muscle on their 2-D screen. In addition, the VR computer records video of the session for later review.



Appendix E

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Research
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Approval – Delegated Review
May 19, 2022

Principal Investigator: Dr. G Robert Laroche
Co-Principal Investigator: Dr. David Westwood
Title: Importance of stereoacuity in a virtual reality model of strabismus surgery
Project #:1027551

On behalf of the IWK Research Ethics Board (IWK-REB), I have reviewed the documents included in this study. I am pleased to confirm the Board's full approval for this research study, effective today.

Please ensure that any agreements, contracts and funding (where applicable) are in place prior to commencing this research.

Best wishes for a successful study.

Yours truly,

[redacted]
Eleanor Fitzpatrick
Co-Chair, Research Ethics Board

This approval includes the following study documents:

Document Name	Version Date
Protocol	2022/04/14
Information and Consent Form	2022/04/07
Data Collection and Secondary Screening	2021/11/30
Data collection form	2022/04/14
Initial screening document	2022/03/28
Phone call script	2021/11/30

The Board's approval for this study will expire one year from the date of this letter (May 19, 2023). To ensure continuing approval, submit a Request for Continuing Review to the Board 2 - 4 weeks prior to the

renewal date. If approval is not renewed prior to the anniversary date, the Board will close your file and you must cease all study activities immediately. To reactivate a study, you must submit a new Initial Submission (together with the usual fee, if applicable) to the IWK-REB and await notice of re-approval.

Please be sure to notify the Board of any of the following:

- Proposed changes to the initial submission (i.e. new or amended study documents)
- Additional information to be provided to study participants
- Material designed for advertisement or publication with a view to attracting participants
- Serious adverse events experience by local participants
- Unanticipated problems involving risks to participants or others
- Sponsor-provided safety information
- Additional Compensation available to participants
- Upcoming audits/inspections by a sponsor or regulatory authority
- Closure of the study (within 90 days of the event)

Approved studies may be subject to internal audit. Should your research be selected for audit, the Board will advise you and indicate any other requests at that time.

Important Instructions and Reminders

Submit all correspondence to Ethics Coordinator, Joanne Street at the address listed at the top of this letter (do not send your response to the IWK-REB Chair or Co-Chair)

Be sure to reference the Board's assigned file number, 1027551 on all communications.
Highlight all changes on revised documents and remember to update version numbers and version dates, include a clean copy of all revised documents.

Research Ethics Board Committee Members		
Jehier	Afifi	Neonatal Pediatrics (Clinical Researcher)
Victoria	Allen	Obstetrics and Gynecology (Clinical Researcher)
Christopher	Blackmore	Surgery (Clinical Researcher) Co-Chair
Carol	Digout	APPHON (Clinical Researcher)
Kellie	Davis	Medical Genetics (Clinical Researcher)
Bryan	Fader	Lay Representative
Eleanor	Fitzpatrick	Nursing (Clinical Researcher), Co-Chair
Zara	Forbrigger	Oncology (Coordinator)
Isabelle	French	Legal Representative
Shannan	Grant	Obstetrics and Gynecology and Pediatrics (Clinical Researcher)
Daddy	Mata-Mbemba	Diagnostic Radiology (Clinical Researcher)
Mari	Somerville	Post-Doctoral Research Fellow
Megan	Thomas	Developmental Pediatrics (Clinical Researcher)
Francois	Tremblay	Pediatric Ophthalmology (Clinical Researcher)

* REB members are not in attendance during the review of their own proposed research involving human subjects or where there is a conflict of interest with the proposed research

This statement is in lieu of Health Canada's Research Ethics Board Attestation: *the Research Ethics Board for*

the IWK Health Centre operates in accordance with:

- Part C Division 5 of the *Food and Drug Regulations* or with the definition in the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*;
- *Natural Health Products Regulations, Part 4 "Clinical Trials Involving Human Subjects"*
- *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*
- *ICH Good Clinical Practice: Consolidated Guideline (ICH-E6)*
- *FWA #: FWA00005630 / IORG #: IORG0003102 / IRB00003719*

Appendix F

Information and Consent/Authorization Form

Importance of stereoacuity in a Virtual Reality model of strabismus surgery

Principal Investigator
G. Robert LaRoche, MD, FRCS(C)
Department of Surgery, IWK Health Centre
Professor of Ophthalmology, Department of Ophthalmology and Visual Sciences, Dalhousie University

Co-Investigators
David Westwood, PhD, Professor, Kinesiology, Dalhousie University

Ryan Cameron, CEO, Electric Puppets (VR program)

Ashley Whelan, MD, Ophthamology Resident, Department of Ophthalmology and Visual Sciences, NSHA and IWK Health Centre

Ron El Hawary MD, MSc, FRCS(C), Professor of Surgery (Orthopaedics)
Professor of Surgery (Neurosurgery), Professor School of Biomedical Engineering, Dalhousie University, Chief of Paediatric Orthopaedics, IWK Health Centre

Dafydd A. Davies MD, MPhil, FRCSC, Pediatric Surgeon, Division Head, Division of Paediatric General and Thoracic Surgery, IWK Health Centre, Assistant Professor, Dalhousie University

Katie MacLellan, OC(C), COMT, Clinical Vision Science program, Dalhousie University

Leah Walsh, OC(C), COMT, MSc, Associate Professor, Clinical Vision Science Program, Dalhousie University

Funding Source:
This study is being funded by Dalhousie University's Department of Surgery and the Department of Ophthalmology at Dalhousie University

Contact
Katie MacLellan OC(C), COMT
Sub-investigator
IWK Eye Care Centre,
Faculty of Graduate Studies, Dalhousie University
KMacLellan@dal.ca

Introduction

You have been invited to take part in this study titled the Importance of stereoacuity in a Virtual Reality model of strabismus surgery. The purpose of this form is to give you more information about the study including the goal of the study, what you will be asked to do, and any risks and benefits of participating. A staff member of our research team will be available to answer any questions you may have. You do not have to participate in the study, but if you chose to do so you can withdraw consent at anytime. Your decision will not affect your care at the IWK health centre in any way.

Why are the researchers doing the study?

This research aims to determine if the longstanding absence of stereopsis (perfect 3D vision) in individuals with strabismus (misalignment of the eyes) impacts how well they can complete a simulated surgical task for strabismus surgery. Our research also aims to determine if repetition helps to improve performance in individuals without stereopsis more so than those with stereopsis. If so, does repetition improve performance to a level similar to those with stereopsis who are close in age. Additionally, our research aims to determine if individuals without measurable 3D vision complete the simulated surgical task using different hand and head movements than individuals with stereopsis. We also are looking to see if individuals without stereopsis feel differently about their fine motor skills after seeing the scored results of this task.

How will the researchers do the study?

This study will include two participant groups: one group of individuals with strabismus and a reported longstanding absence of perfect 3D vision and no measurable 3D vision at time of enrollment in the study, and a second group with perfect 3D vision. All participants will be asked to complete a questionnaire regarding any relevant history to assess if they fit the criteria for this study. Vision and 3D vision testing will also be performed at that time, to identify which group the participant fits.

We plan to recruit 24 subjects, 12 in each group. The two groups will be age matched, meaning that for each participant in one group, there will be a participant within five years of their age in the other group.

There will be several components of this study. After reading over the initial self-questionnaire, participants who do not meet any exclusion critera will review this consent document and have the opportunity to ask any questions about their participation in this study before agreeing to participate. The next part will be a questionnaire, tremor assessment, and eye exam to further establish eligibility in the study. The final part will be the simulated surgical task using VR. All components will take place at the IWK Health Centre.

What will I be asked to do?

If you are interested in taking part in this study, we will review this consent form. You will also be given a copy to keep. You will be given a questionnaire to complete to assess if you are eligible to take part in this study and a member of our study team will conduct

an eye exam to test vision in each eye, eye alignment, 3D vision, and autorefraction (assessment of your eye prescription), a writing/drawing task to assess for tremor and you will complete a questionnaire of relevant eye and health history and a handedness questionnaire.

The task will be first demonstrated on a plastic model, followed by an instructional video with the VR images. You will then put on the VR headset and in the first trial you will have 4 attempts to complete the surgical task using wands as your surgical tools, with no spatial feedback or depth cues from head movements. In the second trial you will have 4 more attempts, in which are free to move your head for potential depth cues.

How long will this take?
The time required to perform all components of the study (including consent, questionnaires, eye exam, plastic model practice, VR examination) will take approximately 2 hours, no more than 3 hours.

What are the burdens, harms, and potential harms?
The eye testing that will be done does not cause any harm. No drops or medicine will be used.

The virtual reality simulation could cause disorientation. Headaches, migraines, or nausea can occur with VR, however these are rare with the VR system we are will be using.

As some information about you will be collected for this study, there is a chance that someone outside the research team could access this information. We will protect your information by using a unique study identifier rather than your name on any data forms. Any files with your name or identifying information will be kept seperately in a private and secure location within the IWK Health Centre.

As with all research projects, there is a chance of some unexpected risk.

How will my privacy be protected?
Your unique study identifiers will be used for all forms completed. There will be no personal identifiable information (such as your name or address) on any data forms, only the unique study identifier. The list connecting your identifier to your name or hospital number will be store separately from all other study records. Any files with your name or identifying information will be kept seperately in a private and secure location within the IWK Health Centre.

Any records that identify you will be kept in a locked cabinet in a locked office. Computer files will be stored on the hospital's network and protected by passwords. The VR data will be accessible to Electric Puppets as a partner on this project. It will be stored on Electric Puppets computers outside the IWK. However, it will not identify you in any way. Electric Puppets will not be given access to identifiers about you.

Only the research team will have access to any of the information recorded for this study, with the following exceptions: the IWK Research Ethics Audit Committee may look at the records to make sure the researchers are performing the research properly; the funders of the project may request a review of study records. In these cases, no identifiable information about you will be allowed to leave the hospital. Only in the unlikely chance that law enforcement officials request your information would it be permitted to leave the IWK Health Centre.

Any presentations or publications that come from this research will not identify you. Any results given will only be a combination of data from everyone who participates.

The records for the study will be kept for five years after the results are published, according to IWK policy. After that time they will be destroyed.

What are the potential benefits?

If you choose to participate in this study, there will likely be no direct benefit to you. You will however likely gain some new insight in your own ability to perform a fine motor task in a new Virtual Reality environment. We hope that the information we gain from this study will help clarify the role of stereopsis in strabismus surgery.

What alternatives to participation do I have?

Your participation in this study is entirely voluntarily. You do not have to participate in the study. It is entirely your choice. If you choose not to participate, it will not affect the care you or your family members receive at the IWK Health Centre.

Can I withdraw from the study?

Even if you agree to participate in the study, you can change your mind at any time and withdraw from the study. If you decide to withdraw, you can request that your data be removed from the study. If you choose to withdraw it will not affect the care you or your family members receive at the IWK Health Centre.

Will the study cost me anything and, if so, how will I be reimbursed?

There will be no costs to you other than the time you spend at your study visit. To thank you for your time we will compensate you for parking costs at the IWK ($7) and we are offering a $8 Tim Hortons gift card.

Are there any conflicts of interest?

Some members of the Eye Clinic are also researchers on this project. However, they will not receive any payments from the study. Whether you participate or not will not change the way the staff take care of you.

This study is part of a bigger project that is designed to develop of VR product for vision testing. If this happens, the IWK Health Centre and your doctor may receive money.

What if I have study questions or problems?
If you have any questions or concerns about the study, you may contact :
Katie MacLellan
KMacLellan@dal.ca

What are my research rights?
Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators or the IWK Health Centre from their legal and professional responsibilities.

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.

If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-8520, Monday to Friday between 8:00a.m. and 4:00p.m.

What about possible profit from commercialization of the study results?
This study is part of a bigger project that may result in products or services for sale. If this happens, participants will not receive any further compensation.

How will I be informed of study results?
If you wish to have a copy of the results of the study, an easy to read summary will be sent to you once it is complete. The summary will only include the overall results, not individual results.

Future Research
We may like to use information collected from you during this study for future research studies on VR vision applications. If you agree to this, the confidentiality of your study records will be protected to the full extent provided by law.

We may like to use information collected from you during this study for future research studies on VR vision applications. If you agree to this, the confidentiality of your study records will be protected to the full extent provided by law.

Study Title: Importance of stereoacuity in a Virtual Reality model of strabismus surgery
Participant ID: _____ Participant Initials: _____

Participant Consent: I have read or had read to me this information and consent/authorization form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks. I understand that I have the right to withdraw from the study at any time without affecting my care in any way. I have received a copy of the Information and Consent/Authorization Form for future reference. I freely agree to participate in this research study.

Name of Participant:(print) _____

Participant (or participant's parent/guardian) Signature:
_____

Date(dd/MMM/yyyy): _____ Time: _____

Study Results: Would you like a copy of the research results? ❒ Yes ❒No

If yes, provide your email address or mailing address:
_____
_____
_____

Future Research Studies: Do you agree that the information collected from you during the study may be used for future research studies? ❒ Yes ❒ No

STATEMENT BY PERSON PROVIDING INFORMATION ON THE STUDY
I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.

Name (print) _____ Position_____

Signature:_____ Date(dd/MM/yyyy):_____ Time: ____

STATEMENT BY PERSON OBTAINING CONSENT
I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Name (print) _____ Position_____

Signature:_____ Date(dd/MM/yyyy):_____ Time: ____